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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,811	03/22/2006	Luppo Edens	GRT/4662-157	4888

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EXAMINER	
SINGH, SATYENDRA K	
ART UNIT	PAPER NUMBER
1657	
MAIL DATE	DELIVERY MODE
11/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/572,811	EDENS ET AL.	
	Examiner	Art Unit	
	SATYENDRA K. SINGH	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 18-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-15 and 18-22* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response (and claim amendments) filed on July 29th 2008 is duly acknowledged.

Claims 1-15 and 20-22 are currently pending in this application.

It is noted that applicants (see remarks, page 7, in particular) have cancelled claims 16 and 17; added new process claims 20-22; and amended the pending claims that upon further considerations necessitate a fresh grouping and/or requirements for election/restrictions.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 4, 5, and 7, drawn to **a process for the proteolytic hydrolysis of a peptide or a polypeptide** as recited in claim 1, wherein said peptide or polypeptide is not hydrolysable by subtilisin.

Group II, claim(s) 2 and 6, drawn to **a process for the proteolytic hydrolysis of a peptide or a polypeptide** as recited in instant claim 2, said peptide or polypeptide comprising the tripeptide motif Glu-Xxx-Pro, Gln-Xxx-Pro, Tyr-Pro-Phe or Tyr-Pro-Trp.

Group III, claim(s) 3, drawn to **a process for the proteolytic hydrolysis of a peptide or a polypeptide**, said peptide or polypeptide comprising at least 30% proline and/or glutamine residues, and with the proviso that the peptide or polypeptide comprises at least 10% proline residues.

Group IV, claim(s) 8, drawn to **a method of using a proline specific endoprotease** to hydrolyze a peptide or polypeptide comprising 4-40 amino acid residues that is not hydrolysable by subtilisin, the method comprising administering a dietary supplement comprised of said proline specific endoprotease for ingestion by a patient in need thereof (taken as a process of providing dietary supplement for ingestion to a patient population in need thereof).

Group V, claim(s) 9, 11, 12 and 18, drawn to **a method of Using a proline specific endoprotease** to hydrolyze proline rich peptides which are brought in relation with psychiatric disorders (taken as process of providing dietary supplement to a specific patient populations in need thereof) as recited in claim 9, as amended.

Group VI, claim(s) 10, drawn to a method of **using a proline specific endoprotease to produce food**, which is devoid of celiac related epitopes, the method comprising digesting food with said proline specific endoprotease (taken as process of making a food product).

Group VII, claim(s) 13, drawn to a **method of using a proline specific endoprotease** as a dietary supplement or a medicament for treatment or prevention of psychiatric disorders selected from the group consisting of autism, schizophrenia, ADHD, bipolar mood disorder and depression as specifically recited in claim 13 (taken as a process of prevention or treatment).

Group VIII, claim(s) 14, drawn to a **method of using a proline specific endoprotease** for the manufacture of a dietary supplement or a medicament for individuals below the age of 25 years, wherein the method comprises administering said supplement or medicament to a patient in need thereof (taken as a process of making a composition and using it for a specific set of patient population).

Group IX, claim(s) 15 and newly added claims 20-22, drawn to a **method of using a proline specific endoprotease** as a dietary supplement or a medicament for treatment or preventing of a "celiac disease linked disorder like autoimmune disorder" as specifically recited in claim 15 as amended (taken as a process of prevention or treatment).

Group X, claim(s) 19, drawn to a **method of using a proline specific endoprotease**, the method comprising adding said proline specific endoprotease to a dietary supplement or a medicament (Note: the claim recitation seems to be incomplete; taken as a process of making a product).

(a) An international or national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those invention involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

(b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) a product and a process specially adapted for the manufacture of said product; or

(2) a product and a process of use of said product; or

(3) a product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) a process and an apparatus or means specifically designed for carrying out said process; or

(5) a product, a process specially adapted for the manufacture of the said product and an apparatus or means specifically designed for carrying out said process.

(c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

The groups of inventions as recited in **groups (I-X)** do not fall within any of the categories mentioned above.

PCT Rule 13.2 does not provide for multiple compositions or multiple methods of use within a single application. Thus, the first appearing composition is combined with a corresponding first method of use and the additional composition and method claims each constitute a separate group.

In addition to the requirement that a group of inventions must belong to one of the specific categories provided by PCT Rule 13.2, the inventions in the category, such as a composition and a method of use of the composition, must have a special technical feature that unites them. See Patent Rules 1.475, where a special technical feature is a contribution OVER THE PRIOR ART.

Thus, the inventions listed as Groups (I-X) do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features as demonstrated above. Since the product or composition used in the process inventions AS CLAIMED (i.e. special technical feature being the "proline specific endoproteases" which are used in all the methods of making and using as amended) is known in the art, see **Edens et al** (2002, WO 02/45523; IDS, abstract, page 12, examples 3, and 9-11, in particular), no special technical feature unites these inventions in a category.

The expression "special technical feature" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art (PCT Rule 13.2). Thus, a feature found in the prior art cannot be considered to be a special technical feature.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Species Election

This application contains claims directed to the patentably distinct species as listed below:

A. If the invention of **group V** is elected, claim 9 recites the following species of disorders: applicants are required to elect a single disorder for examination purposes.

autism, schizophrenia, ADHD, bipolar mood disorder, depression, type 1 diabetes, dermatitis herpetiformis, autoimmune thyroiditis, collagen diseases, autoimmune alopecia. autoimmune hepatitis and IBS

B. If the invention of **group VII** is elected, claim 13 recites the following species of disorders: applicants are required to elect a single disorder for examination purposes.

autism, schizophrenia, ADHD, bipolar mood disorder and depression

C. If the invention of **group IX** is elected, claim 15 recites the following species of disorders: applicants are required to elect a single disorder for examination purposes.

type 1 diabetes, dermatitis herpetiformis, autoimmune thyroiditis, collagen diseases, autoimmune alopecia. autoimmune hepatitis and IBS

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Pursuant to PCT Rule 13.2 and PCT Administrative Instructions, Annex B, Part 1(f)(I)(B)(2), the species are not art-recognized equivalents.

Applicant is required to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Currently, claims 1-8, 10-12, 14 and 18-22 are deemed generic.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the

case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Response to Applicant's Arguments

Applicant's remarks (see remarks, page 7, 1st paragraph, in particular) that "*...none of the groups listed on pages 2-3 of the Action mention treatment and prevention of celiac disease linked disorders*" is not found to be accurate. The previous action sent by the examiner did provided, on page 3, group X (claim 15) which was taken as being directed to a process for prevention or treatment using the proline specific endoprotease as claimed in the invention before the current claim amendments were submitted by applicants. Moreover, applicant's response with traverse is considered inadequate because it failed to identify a single group of invention that was elected for the examination purposes. However, upon further consideration and in view of substantial amendments made by applicants to the pending claims (for example, changing product claims 11 and 12 into process claims, and adding new claims 20-22), current office action with new election/restriction requirement is deemed appropriate.

NOTE: applicants are advised to use correct the Sr. No. (10/572,811) for the instant application while responding to the office action in future, which has been incorrectly noted by applicants as being 10/572,157 on the headers (see remarks, pages 2-7, in particular), and which has been taken by the examiner as minor typographical error.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SATYENDRA K. SINGH whose telephone number is (571)272-8790. The examiner can normally be reached on 9-5MF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sandra Saucier/
Primary Examiner, Art Unit 1651

/Satyendra K. Singh/
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